Adverse events and potentially preventable deaths in Dutch hospitals

Zegers, M.; Bruijne, M.C. de; Wagner, C.; Hoonhout, L.H.F.; Waaijman, R.; Smits, M.; Groenewegen, P.P.

Published in:
Quality & Safety in Health Care

Adverse events and potentially preventable deaths in Dutch hospitals: results of a retrospective patient record review study

M Zegers, M C de Bruijne, C Wagner, et al.

Qual Saf Health Care 2009 18: 297-302
doi: 10.1136/qshc.2007.025924

Adverse events and potentially preventable deaths in Dutch hospitals: results of a retrospective patient record review study

M Zegers,[1] M C de Bruijne,[2] C Wagner,[1,2] L H F Hoonhout,[2] R Waaijman,[2] M Smits,[1] F A G Hout,[2] L Zwaan,[2] I Christiaans-Dingelhoff,[2] D R M Timmermans,[2] P P Groenewegen,[1] G van der Wal[2]

► Additional appendices are published online only at http://qshc.bmj.com/content/vol18/issue4

[1] NIVEL, Netherlands Institute for Health Services Research, Utrecht, the Netherlands; [2] EMGO Institute, VU University Medical Centre, Amsterdam, the Netherlands

Correspondence to: M Zegers, NIVEL, Netherlands Institute for Health Services Research, PO Box 1568, 3500 BN Utrecht, the Netherlands; m.zegers@nivel.nl

Accepted 14 June 2008

ABSTRACT

Objective: This study determined the incidence, type, nature, preventability and impact of adverse events (AEs) among hospitalised patients and potentially preventable deaths in Dutch hospitals.

Methods: Using a three-stage retrospective record review process, trained nurses and doctors reviewed 7926 admissions: 3983 admissions of deceased hospital patients and 3943 admissions of discharged patients in 2004, in a random sample of 21 hospitals in the Netherlands (4 university, 6 tertiary teaching and 11 general hospitals). A large sample of deceased patients was included to determine the occurrence of potentially preventable deaths in hospitals more precisely.

Results: One or more AEs were found in 5.7% (95% CI 5.1% to 6.4%) of all admissions and a preventable AE in 2.3% (95% CI 1.9% to 2.7%). Of all AEs, 12.8% resulted in permanent disability or contributed to death. The proportion of AEs and their impact increased with age. More than 50% of the AEs were related to surgical procedures. Among deceased hospital patients, 10.7% (95% CI 9.8% to 11.7%) had experienced an AE. Preventable AEs that contributed to death occurred in 4.1% (95% CI 3.5% to 4.8%) of all hospital deaths. Extrapolating to a national level, between 1482 and 2032 potentially preventable deaths occurred in Dutch hospitals in 2004.

Conclusions: The incidence of AEs, preventable AEs and potentially preventable deaths in the Netherlands is substantial and needs to be reduced. Patient safety efforts should focus on surgical procedures and older patients.

Previous retrospective record review studies in several countries have shown that 2.9% to 16.6% of patients in acute care hospitals experience one or more adverse events (AEs) and in 4.5–20.8% of the AEs, the patient dies.[1–13] Approximately 50% of the AEs are judged to be preventable. An AE is defined as an unintended injury that results in temporary or permanent disability, death or prolonged hospital stay, and is caused by healthcare management rather than by the patient's underlying disease process.[2 5 8 13] Variation in the incidence of AEs will be partly determined by policies and characteristics at hospital level (within country variation, between hospitals), partly by policies at national level (between country variation) and partly by differences in methodology of the studies.[14 15]

The occurrence of AEs in Dutch hospitals has not been systematically studied. Insight in preventable AEs can increase the sense of urgency and offer a starting point for specific interventions to improve patient safety, whereas insight in unpreventable AEs may help prioritise research areas. Therefore, we conducted a retrospective patient record review study to determine the incidence, type, nature, impact and preventability of AEs among hospitalised patients in the Netherlands. This study is the largest population-based study carried out in Europe on the occurrence of AEs and reflects the increasing attention paid to patient safety across Europe. The protocol and instruments were based on the Canadian Adverse Events Study.[2]

METHODS

Study design and setting

The design and methods have been described in detail elsewhere.[16] We performed a retrospective patient record review study in a random stratified sample of 21 of the 101 Dutch hospitals: 4 university, 6 tertiary teaching and 11 general hospitals. To measure the difference in incidence between hospital types, the sample of hospitals was stratified for hospital type. Proper representation of urban and rural settings in the sample was verified. Eligible hospitals had at least 200 beds, an emergency department and an intensive care unit. A large subsample of deceased hospital patients was included to determine more precisely than in previous studies the occurrence of potentially preventable deaths in hospitals.

The power calculation of this study was based on the results of the Canadian Adverse Events Study.[2] Assuming an incidence of AEs of 8%, we required a sample of 4200 hospital admissions of discharged patients and a sample of 4200 admissions of deceased patients ($\beta = 0.20$, $\alpha = 0.05$) to estimate a 95% confidence interval of 0.5% on both sides. To measure the difference in incidence between hospital types, a selection of 800 hospital admissions per hospital type was necessary to detect a difference from 2% to 3% by an incidence between 3% and 7%.

From each hospital, we randomly selected 200 admissions (>24 h stay) of discharged patients and 200 (or fewer if the total of patients who died in 2004 was lower) admissions of deceased hospital patients in 2004, excluding admissions to psychiatry and obstetrics and of children <1 year.[16]

Box 1 Definitions and outcome measures[16]

Adverse event determination

AE determination was based on the presence of three criteria:

1. an unintended (physical and/or mental) injury, which
2. resulted in temporary or permanent disability, death or prolongation of hospital stay, and was
3. caused by healthcare management rather than the patient's disease.

To determine whether the injury was caused by healthcare management or the disease process (criterion 3) a six-point scale was used:

1. (Virtually) no evidence for management causation
2. Slight to modest evidence of management causation
3. Management causation not likely (less than 50/50, but "close call")
4. Management causation more likely (more than 50/50, but "close call")
5. Moderate to strong evidence of management causation
6. (Virtually) certain evidence of management causation

Causation scores of 4–6 were classified as AEs.

Timing of AEs

The index hospital admission was the admission sampled. AEs were included if they occurred during the index admission and were detected during or within 12 months after the index admission. AEs were also included if they were related to hospital admissions in the same hospital in the 12 months preceding the index admission, but were not detected until the index admission.

Preventability

The degree of preventability of AEs was measured on a six-point scale, grouped into three categories:

- No preventability

1. (Virtually) no evidence for preventability

- Low preventability

2. Slight to modest evidence of preventability
3. Preventability not quite likely (less than 50/50, but "close call")

- High preventability

4. Preventability more than likely (more than 50/50, but "close call")
5. Strong evidence of preventability
6. (Virtually) certain evidence of preventability

AEs with a preventability score of 4–6 were defined as preventable AEs.

Potentially preventable hospital deaths

Potentially preventable hospital deaths were defined as highly preventable AEs which contributed to death during the hospital admission. The adjective "potentially" is used because of the multifactorial nature of hospital deaths and the retrospective assessment of causality.

Life expectancy

The doctor reviewers estimated the life expectancy of the deceased patients for the situation that the hospital admission would have evolved without an AE, taking into account the health status of the patient as described in the patient records and using their professional judgement.

Review of patient records

The nursing, medical and, if available, outpatient record of the sampled admissions were reviewed by 66 trained nurses and 55 trained doctors in a three-stage review process between August 2005 and October 2006. In the first stage, a nurse screened the records by using 18 screening criteria indicating potential AEs (see online appendix A). In the second stage, two doctors independently reviewed the records with one or more positive screening criteria. Based on a standardised procedure they determined presence, nature, impact, clinical process and degree of preventability of the AEs. Also the life expectancy in case the AE had not occurred was estimated for deceased patients with AEs (box 1). If there was disagreement about the presence and/or preventability of an AE between the two doctors' reviews, they undertook a consensus procedure (stage 3). If they could not reach a consensus, a third trained doctor reviewer gave the final judgement.[16]

Reliability study

To assess the reliability of the first stage of the record review process, a random sample of 415 records was independently reviewed by a second nurse. To assess the reliability of the final judgement (including any consensus and third review if applicable) of the doctors' review, a random sample of 119 records was reviewed by a second pair of doctors.[16]

Statistical analysis

We calculated the national weighted incidence of AEs and preventable AEs in Dutch hospitals with 95% confidence intervals, corrected for the over-representation of patients admitted to a university hospital and for the over-representation of patients who died in hospital, using the "complex sample" option in SPSS V14.0. The sample weight was the inverse of the probability of being included in the sample owing to the sample design. It was calculated as N/n, where N = the number of elements in the population and n = the number of elements in the sample (see online appendix B). After weighting for the sampling frame, the total study sample (discharged and deceased patients) and the subsample of deceased patients were representative for the Dutch population of hospitalised patients and for the Dutch population of deceased hospital patients,

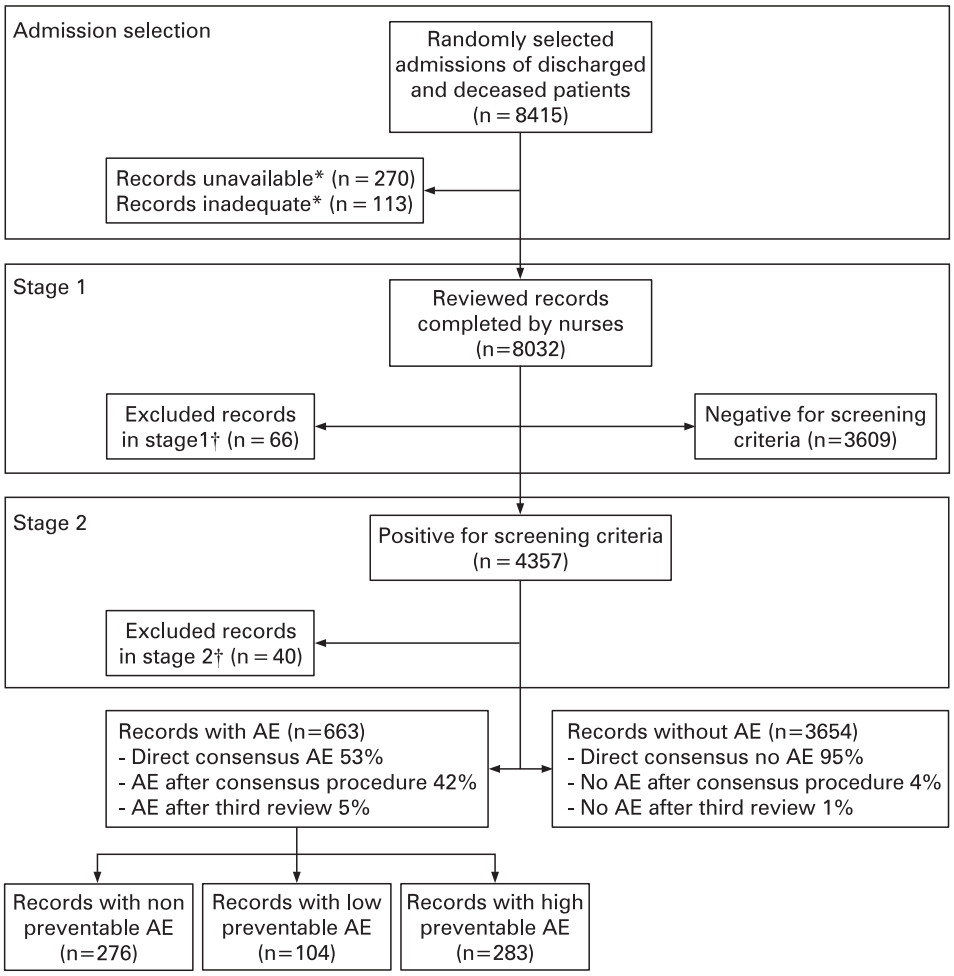

Figure 1 Flowchart of the review process. *Records were considered not available when the nursing and/or medical record of the index admission was missing or because the patient was hospitalised during the study. For one hospital, only the records of hospital deaths were included because of hospital-related logistical reasons. Records were considered inadequate if they: did not comply with the selection criteria; contained inadequate and/or incomplete documentation for AE determination; were sampled twice or wrongly; or the admission was too short (patient came with cardiac arrest to the emergency department or outpatient resuscitation). †Patient was hospitalised during the study; inadequate and/or incomplete patient record documentation; did not comply with the selection criteria; sampled twice; incomplete record review.

respectively (see online appendix C). The characteristics of the AEs, such as disability and classification, and patient and admission characteristics were also assessed using weights to adjust for the sampling frame. The analysis for the subsample of deceased patients was only weighted for the over-representation of patients admitted to a university hospital.

The inter-rater agreement of the review process between nurses for finding screening criteria and for the determination of

Table 1 Weighted incidence of adverse events (AEs) in patients admitted to Dutch hospitals in 2004 by hospital type, both for the total sample (discharged patients and deceased patients) and for the subgroup of deceased patients

	Hospital type			
	University	Tertiary teaching	General	Total sample
Total sample* (n = 7926)				
No of records reviewed	1378	2342	4206	7926
No of records with AEs	171	187	305	663
Weighted AE incidence, % (95% CI)	7.6 (5.9 to 9.8)	6.7 (5.5 to 8.1)	4.8 (4.1 to 5.7)	5.7 (5.1 to 6.4)
No of records with preventable AEs	37	90	156	283
Weighted preventable AE incidence, % (95% CI)	1.6 (0.9 to 2.9)	2.8 (2.1 to 3.8)	2.2 (1.7 to 2.8)	2.3 (1.9 to 2.7)
Deceased patients† (n = 3983)				
No of records reviewed	780	1155	2048	3983
No of records with AEs	129	110	208	447
Weighted AE incidence, % (95% CI)	16.5 (14.1 to 19.3)	9.5 (8.0 to 11.4)	10.2 (8.9 to 11.5)	10.7 (9.8 to 11.7)
No of records with preventable AEs	28	58	114	200
Weighted preventable AE incidence, % (95% CI)	3.6 (2.5 to 5.2)	5.0 (3.9 to 6.4)	5.6 (4.7 to 6.6)	5.2 (4.5 to 5.9)
No of records with preventable AEs that contributed to the death of the patient	19	48	90	157
Weighted incidence of preventable AEs that contributed to the death of the patient, % (95% CI)	2.4 (1.6 to 3.8)	4.2 (3.1 to 5.5)	4.4 (3.6 to 5.4)	4.1 (3.5 to 4.8)

*Incidence rates and 95% CIs were weighted for oversampling of deceased patients and of patients admitted to a university hospital.
†Incidence rates and 95% CIs were weighted for oversampling of deceased patients admitted to a university hospital.

Table 2 Adverse events (AEs) by admission department: number of reviewed admissions, weighted AE incidence per department and proportion of AEs that were preventable

Admission department	No of reviewed admissions (N = 7926)	Incidence of AEs (%)*	Preventable AEs (%)*
Surgical			
Neurosurgery	116	9.5	15.4
Urology	221	7.8	32.0
Surgery	1443	7.7	40.1
Ophthalmology	51	5.8	40.0
Ear, nose and throat	198	5.2	22.2
Orthopaedics	496	5.1	52.4
Gynaecology	135	4.7	50.0
Total	2660	6.8 (95% CI 5.7 to 7.8)	39.5
Non-surgical			
Intensive care	373	9.4	50.0
Internal medicine	1950	5.4	25.7
Cardiology	1165	4.9	32.7
Lung diseases	787	5.4	71.0
Neurology	767	3.6	61.9
Paediatrics	142	1.6	50.0
Other medical	82	NA	NA
Total	5266	4.8 (95% CI 4.1 to 5.7)	40.3

NA, not applicable
*Percentages were weighted for oversampling of deceased patients and of patients admitted to a university hospital.

AEs and their preventability between two pairs of doctors was expressed as a κ statistic with 95% confidence intervals and as a percentage of records for which there was agreement.

RESULTS

Incidence of AEs among hospitalised patients

Of the 8415 sampled records, 8032 were eligible for a first-stage review (screening success rate was 95%) (fig 1). In 54% of these records one or more screening criteria were identified (appendix A). In the second stage, the reviewing doctors identified 744 AEs in 663 hospital admissions. In 70 hospital admissions (10.6% of 663), two or more AEs were found. In all, 504 AEs were found in 447 deceased and 240 AEs in 216 discharged patients. After weighing for the sampling frame, the national incidence of AEs among hospitalised patients was 5.7% (95% CI 5.1% to 6.4%) and the incidence of preventable AEs was 2.3% (95% CI 1.9% to 2.7%) (table 1).

Incidence rates of AEs were significantly higher in university hospitals than in general hospitals ($p<0.001$). Although not statistically significant, the incidence of preventable AEs was lower in university hospitals compared with the other types of hospital.

Of 744 AEs, 39.6% were considered preventable. More than half of all AEs (56.8%) resulted in no or minimal physical impairment or disability. However, 5.0% resulted in permanent disability and 7.8% contributed to death. The incidence of AEs was higher in surgical departments than in non-surgical departments (table 2).

A quarter of all AEs occurred in the previous 12 months and were detected in the index admission in the same hospital. The majority of AEs (63%) occurred and were detected during the index admission, whereas 12% occurred during the index admission and were detected within 12 months after the index admission.

More than half (54%) of all AEs were related to surgical procedures. Almost all AEs related to the diagnostic process were highly preventable and 23% contributed to death (table 3). The proportion of AEs, preventable AEs and degree of disability increased with age (table 4).

Table 3 Adverse events (AEs) by clinical process and proportions judged preventable, leading to permanent disability (excluding death) and contributed to death

Classification	No of AEs	Distribution of AEs (column %*)	Preventable (row %*)	Permanent disability (row %*)	Deaths (row %*)
Surgery (events related to an operation or occurring within 30 days after an operation)	297	54.2	34.4	4.0	5.1
Drug/fluid (eg, side effects, allergic reactions, anaphylaxis)	157	15.3	31.2	2.6	10.5
Medical procedure (eg, central catheters, endoscopies, pacemakers, intervention radiology)	135	17.0	27.9	9.3	7.0
Diagnostic (eg, missed, delayed or inappropriate diagnostic process)	80	6.3	84.4	12.9	22.6
Other clinical management (including nursing care and allied healthcare)	56	3.7	78.9	0	15.8
Discharge (eg, inappropriate discharge)	4	1.4	100.0	0	0
Other (eg, fall)	15	2.1	81.8	0	9.1
Total	744	100.0	39.6	5.0	7.8

*Percentages were weighted for oversampling of deceased patients and of patients admitted to a university hospital.

Table 4 Adverse events (AEs) by age: number of reviewed admissions, number of admissions with an AE and proportions judged preventable, contributed to permanent disability (excluding death) and death

Age	No of reviewed admissions	No of admissions with AE(s)	Percentage of AEs†	Preventable (row %†)	Permanent disability (row %†)	Deaths (row %†)
1–18	330	7	1.7	20.0	0	0
19–40	660	38	5.0	40.0	7.4	1.9
41–65	2332	180	5.5	37.5	2.4	4.3
66–79	2582	250	6.1	39.9	4.3	12.3
80+	2013	188	8.2	46.2	9.8	15.2
Total	7917*	663	5.7	39.9	5.0	8.6

*Date of birth was missing for nine patients.
†Percentages were weighted for oversampling of deceased patients and of patients admitted to a university hospital.

Table 5 Estimated life expectancy of deceased patients with adverse events (AEs), preventable AEs and potentially preventable AEs that were associated with death

Life expectancy	Distribution AEs (column %*)	Preventable AEs (column %*)	Potentially preventable deaths (column %*)
Some days	2.3	1.5	0.6
Some weeks	9.2	6.3	4.9
Some months	14.3	11.2	9.2
6–12 months	23.5	24.9	26.4
1–5 years	24.4	28.3	31.3
5–10 years	10.6	10.7	12.3
10–20 years	2.6	1.5	1.8
More than 20 years	1.6	3.4	3.7
Unable to determine	10.8	11.2	8.6
Missing, NA	0.7	1.0	1.2
Total	100	100	100

NA, Not of application
*Percentages were weighted for oversampling of deceased patients admitted to a university hospital.

Incidence of AEs among deceased patients

The incidence of AEs and preventable AEs in the subsample of deceased patients was 10.7% (95% CI 9.8% to 11.7%) and 5.2% (95% CI 4.5% to 5.9%), respectively (table 1). The incidence of preventable AEs contributing to death among deceased patients was 4.1% (95% CI 3.5% to 4.8%). In 2004, 42 329 patients died in Dutch hospitals, amounting to 1735 (95% CI 1482 to 2032) potentially preventable hospital deaths.

Compared with the total hospital population, AEs among deceased patients were more often preventable (47.7% vs 39.6%) and were more often related to the diagnostic process (14.8% vs 6.3%). Almost half (49.1%) of the deceased patients with a potentially preventable AE that contributed to death had an estimated potential life expectancy of more than 1 year had the potentially preventable AE not have occurred. In 11% of the cases the life expectancy could not be determined (table 5).

Agreement between reviewers

The reliability of the assessment of screening criteria by nurses was good (κ 0.62; 95% CI 0.54 to 0.69; 82% agreement). The reliability of determination of AEs was only fair (κ 0.25; 95% CI 0.05 to 0.45; 76% agreement), and it was moderate for determination of preventability of AEs (κ 0.40; 95% CI 0.07 to 0.73; 70% agreement).

DISCUSSION

The present study found that in 5.7% of all Dutch hospital admissions one or more AEs occurred of which 39.6% were preventable. Of all AEs, 12.6% resulted in permanent disability or contributed to death. More than half of the AEs were related to surgical procedures; the proportion of (preventable) AEs and their impact increased with age. Among deceased patients, 10.7% had experienced an AE, and in 4.1% a preventable AE contributed to death, amounting to 1735 potentially preventable hospital deaths in the Netherlands in 2004.

More AEs, but fewer preventable AEs, occurred in university hospitals than in tertiary teaching and general hospitals. Tertiary teaching hospitals in the Netherlands provide highly specialised care and train doctors in collaboration with university hospitals. The level of care given is between that given in a university hospital and in a general hospital. Generally, university hospitals and to some extent tertiary teaching hospitals treat more complex patients with more complex care.[17] This may explain the higher incidence rate of AEs with lower preventability in university hospitals. The higher proportion of AEs among older patients may be explained primarily by the clinical complexity of their care rather than an age-based discrimination.[18]

The incidence of AEs in the Netherlands is substantial, although at the lower end of the range of results from previous retrospective patient record studies; lower incidence rates were reported only in the USA (table 6). However, these studies assessed negligence rather than preventability, which on the one hand may have led to a more defensive assessment. The

Table 6 Retrospective record review studies on the occurrence of (preventable) AEs of hospitalised patients between 1984 and 2005

Study	Setting	Admissions with ⩾1 AE* % (95% CI)	AEs that were preventable† % (95% CI)	AEs that were associated with death % (95% CI)	Admissions associated with potentially preventable death (%)
Present study	21 Dutch hospitals, 7926 hospital admissions (2004)	5.7 (5.1 to 6.4)	39.6	7.6	0.12
Andres *et al*[19]	24 Spanish hospitals, 5624 hospital admissions (2005)	8.4 (7.7 to 9.1)	42.6	4.4	0.19 **
Michel *et al*[8]	7 hospitals in France, 778 hospital admissions (2002)	14.5	27.6	NR	NR
Schioler *et al*[10]	17 hospitals in Denmark, 1097 hospital admissions (2001)	9.0	40.4	4.9	0.178§
Baker *et al*[2]	20 Canadian hospitals, 3745 hospital admissions (2000)	7.5 (5.7 to 9.3)	36.9	20.8	0.66 ¶
Vincent *et al*[12]	2 hospitals in London, England, 1014 hospital admissions (1998)	10.8	48	8	0.41§
Davis *et al*[4 5]	13 hospitals in New Zealand, 6579 hospital admissions (1998)	12.9	37.1	4.5	0.28 **
Thomas *et al*[11]	28 hospitals in Utah and Colorado, 14 700 hospital admissions (1992)	2.9 (0.2)***	50	6.6	0.13 **
Wilson *et al*[13]	28 hospitals in New South Wales and South Australia, 14 179 hospital admissions (1992)	16.6 (15.2 to 17.9)	51.2	4.9	0.55 **
Brennan *et al*[1] Leape *et al*[3]	51 hospitals in New York, 30 195 hospital admissions (1984)	3.7 (3.2 to 4.2)	27.6‡	13.6	0.26 **

NR, not reported
*Most of the studies used causation score ⩾4, except Davis *et al*[4 5] and Wilson *et al*.[13] They used causation score ⩾2. Not all studies reported 95% CIs.
†All studies reported on high preventable AEs (preventability score ⩾4).
‡ Measured negligence instead of preventability.
¶Reported.[2]
§Estimated by calculation: proportion of AEs × proportion of preventable AEs × proportion that contributed to death.
**Estimated by calculation: proportion of AEs × proportion of preventable AEs that contributed to death.
***SD.

conservative level for causation (≥4) may have resulted in lower incidence estimates than in studies using level 2 as a threshold.[4 5 13 14] On the other hand, we only included patient records for which both the nursing and the medical records were present. This may have led to higher estimates, because in almost 90% of our patient records with screening criteria indicating potential AEs, valuable information was detected in the nursing record. A further explanation of the lower incidence of AEs (and the rate of potentially preventable deaths) in our study could be that the review process with two independent doctor reviewers per record has led to a stricter assessment.

Our study has several limitations. We retrospectively determined the potentially preventable deaths and life expectancy of deceased patients in case the AE had not occurred, based on information in hospital records. It is difficult to estimate the probability of death given that the error was not made.[6] The reviewers could estimate the life expectancy in 81% of the cases, but the results must be treated with caution. In addition, moderate reliability of the review process is a well-known problem of record review studies to identify AEs and their preventability, in which κ values ranged from 0.2 to 0.6.[1 5 8 13 20 21] We aimed to improve the reliability of the review process by:

- intensifying the training of reviewers;
- including paediatricians and neurologists as reviewers in addition to general internists and surgeons;
- using two doctors instead of a single doctor reviewer;
- continuous availability of expert consultation from 18 medical specialties;
- frequently updating and communicating a frequently asked questions list for reviewers;
- by using electronic review forms.[16]

However, the level of agreement (κ value) between two pairs of doctors in this study was not better than in other studies. The high number of reviewers and the high proportion of often complex cases of hospital deaths may have led to lower reliability. Another general weakness of all retrospective studies is hindsight bias.[22] Knowing the outcome and its severity may influence judgement of causation and preventability. In the present study, this could have led to an overestimation of preventable AEs that contributed to the patient's death, as judged by the reviewers.

Although judgement of presence of AEs is difficult, retrospective patient record studies are currently the best method available to assess incidence of AEs.[23] The results provide urgently needed insight in the current state of patient safety and possibilities for improvement of patient safety and are therefore generally highly appreciated.

Before 2004, there was no widespread public awareness of patient safety in the Netherlands. The results of this study have provided the basis for a patient safety action campaign for hospitals "Prevent harm, work safely", which started in 2008 and will run until 2012.[24]

Sufficiently powered studies, or analyses of pooled data from comparable international studies, are needed to get more insight in the incidence of (preventable) AEs for specific specialties or patient groups in order to develop more effective interventions to improve patient safety. An approach that combines record review with prospective methods, in which clinical staff are interviewed about the origin of the AE, will give a more complete picture of (preventable) AEs and organisational and human causal factors.[8 25] To prevent highly preventable AEs, such as AEs related to the diagnostic process, interventions to optimise healthcare procedures and multidisciplinary management are of special interest. AEs currently defined as unpreventable require research to develop new techniques to make them preventable in the future.

Acknowledgements: We would like to thank everyone who contributed to the study: the nurses and doctors who reviewed the patient records, E van Triest for the coordination of the data collection, the 21 participating hospitals and their staff who facilitated the patient records, and P Spreeuwenberg for statistical assistance. The instruments and protocol originated from the Canadian Adverse Events study. We thank G Ross Baker for his advice.

Funding: The Dutch Patient Safety Research Program was initiated by the Orde van Medisch Specialisten [Dutch Society of Medical Specialists] and the Dutch Institute for Healthcare Improvement (CBO) with financial support from the Ministry of Health, Welfare and Sport. The programme is being carried out by EMGO Institute/VUmc and NIVEL.

Competing interests: None.

REFERENCES

1. **Brennan TA,** Leape LL, Laird NM, *et al*. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. *New Engl J Med* 1991;**324**:370–6.
2. **Baker GR,** Norton PG, Flintoft V, *et al*. The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. *CMAJ* 2004;**170**:1678–86.
3. **Leape LL,** Brennan TA, Laird N, *et al*. The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. *New Engl J Med* 1991;**324**:377–84.
4. **Davis P,** Lay-Yee R, Briant R, *et al*. Adverse events in New Zealand public hospitals II: preventability and clinical context. *N Z Med J* 2003;**116**:U624.
5. **Davis P,** Lay-Yee R, Briant R, *et al*. Adverse events in New Zealand public hospitals I: occurrence and impact. *N Z Med J* 2002;**115**:U271.
6. **Hayward RA,** Hofer TP. Estimating hospital deaths due to medical errors: preventability is in the eye of the reviewer. *JAMA* 2001;**286**:415–20.
7. **Jarman B,** Gault S, Alves B, *et al*. Explaining differences in English hospital death rates using routinely collected data. *BMJ* 1999;**318**:1515–20.
8. **Michel P,** Quenon JL, de Sarasqueta AM, *et al*. Comparison of three methods for estimating rates of adverse events and rates of preventable adverse events in acute care hospitals. *BMJ* 2004;**328**:199.
9. **Park RE,** Brook RH, Kosecoff J, *et al*. Explaining variations in hospital death rates. Randomness, severity of illness, quality of care. *JAMA* 1990;**264**:484–90.
10. **Schioler T,** Lipczak H, Pedersen BL, *et al*. [Incidence of adverse events in hospitals. A retrospective study of medical records] [Article in Danish]. *Ugeskr Laeger* 2001;**163**:5370–8.
11. **Thomas EJ,** Studdert DM, Burstin HR, *et al*. Incidence and types of adverse events and negligent care in Utah and Colorado. *Med Care* 2000;**38**:261–71.
12. **Vincent C,** Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. *BMJ* 2001;**322**:517–19.
13. **Wilson RM,** Runciman WB, Gibberd RW, *et al*. The Quality in Australian Health Care Study. *Med J Aust* 1995;**163**:458–71.
14. **Thomas EJ,** Studdert DM, Runciman WB, *et al*. A comparison of iatrogenic injury studies in Australia and the USA. I: Context, methods, casemix, population, patient and hospital characteristics. *Int J Qual Health Care* 2000;**12**:371–8.
15. **Runciman WB,** Webb RK, Helps SC, *et al*. A comparison of iatrogenic injury studies in Australia and the USA. II: Reviewer behaviour and quality of care. *Int J Qual Health Care* 2000;**12**:379–88.
16. **Zegers M,** Bruijne MC de, Wagner C, *et al*. Design of a retrospective patient record study on the occurrence of adverse events among patients in Dutch hospitals. *BMC Health Serv Res* 2007;**7**:27–38.
17. **Association of Tertiary Medical Teaching Hospitals**. http://www.stz-ziekenhuizen.nl/english.html (accessed 12 Oct 2007).
18. **Thomas EJ,** Brennan TA. Incidence and types of preventable adverse events in elderly patients: population based review of medical records. *BMJ* 2000;**320**:741–4.
19. **Andres JMA,** Remon CA, Burillo JV, *et al*. *National study on hospitalisation-related adverse events. ENEAS 2005*. Madrid, Ministry of Health and Consumer Affairs, 2006.
20. **Thomas EJ,** Lipsitz SR, Studdert DM, *et al*. The reliability of medical record review for estimating adverse event rates. *Ann Intern Med* 2002;**136**:812–6.
21. **Localio AR,** Weaver SL, Landis JR, *et al*. Identifying adverse events caused by medical care: degree of physician agreement in a retrospective chart review. *Ann Intern Med* 1996;**125**:457–64.
22. **Fischhoff B.** Hindsight not equal to foresight: the effect of outcome knowledge on judgment under uncertainty. *J Exp Psychol Hum Percept Perform* 1975;**1**:288–99.
23. **Lilford RJ,** Mohammed MA, Braunholtz D, *et al*. The measurement of active errors: methodological issues. *Qual Saf Health Care* 2003;**12**(Suppl 2):ii8–12.
24. **Nederlandce Vereniging van Ziekenhuizen**, Orde van Medisch Specialisten, Landelijk Expertisecentrum Verpleging & Verzonging, *et al*. [Patient safety programme prevent injuries, work safely in Dutch hospitals.] [In Dutch]. Utrecht 2007.
25. **Neale G,** Chapman EJ, Hoare J, *et al*. Recognising adverse events and critical incidents in medical practice in a district general hospital. *Clin Med* 2006;**6**:157–62.

APPENDIX

Appendix A

Table A1 Screening criteria applied in stage 1 to 3983 records of deceased patients and 3943 records of discharged patients and the proportion of hospital admissions positive for each criterion*

Criteria	Description	Deceased patients†(%)	Discharged patients† (%)	Total sample‡ (%)
1	Unplanned admission before index admission (admission reasons are related to the index admission)	24	15	15
2	Unplanned readmission after discharge from index admission	0	13	12
3	Hospital-incurred patient injury (permanent or temporary injury obtained (acquired) during index admission)	16	7	7
4	Adverse drug reaction	7	4	4
5	Unplanned transfer from general care to (an) intensive care (unit)	13	2	2
6	Unplanned transfer to another acute care hospital (after unexpected deterioration of the patient)	0	0	0
7	Unplanned return to the operating room	7	3	3
8	Unplanned removal, injury or repair of organ during surgery	4	2	2
9	Hospital-acquired infection or sepsis	21	6	7
10	Other patient complication	16	3	3
11	Development of neurological deficit not present on admission	5	1	1
12	Unexpected death	47	0	2
13	Cardiac or respiratory arrest	4	0	0
14	Injury related to abortion or delivery	0	0	0
15	Inappropriate discharge to home	0	1	0
16	Dissatisfaction with care documented in the medical record	6	3	4
17	Documentation or correspondence indicating litigation	3	1	1
18	Any other undesirable outcome not covered above	13	8	9
Percentage of records with screening criteria		70	39	54

*More than one criterion could be identified for one hospital admission.
†Weighted for oversampling of patients admitted to a university hospital.
‡Weighted for oversampling of deceased patients and of patients admitted to a university hospital.

Appendix B

Weighting proportions

The calculation of the weighting proportions accounts for the sampling strategy. The sampling weight was the inverse of the probability of being included in the sample owing to the sampling design. It accounts for the proportion of hospital admissions in the three hospital types and the proportion of discharged and deceased patients in the Dutch population of hospital admissions compared with the proportion in this study.

Table B1 Proportions of hospital admissions for discharged status and hospital type

	Proportion in Dutch population (%)	Proportion in this study (%)
Discharge status		
Deceased	3	50
Discharged	97	50
Hospital type		
University	13	17
Tertiary teaching	28	30
General	58	53

Table B2 Weighting proportions for the different sampling strata

Stratum	Weighting factor
Deceased patients admitted to a university hospital	0.038
Deceased patients admitted to a tertiary teaching hospital	0.063
Deceased patients admitted to a general hospital	0.072
Discharged patients admitted to a university hospital	0.771
Discharged patients admitted to a tertiary teaching hospital	0.962
Discharged patients admitted to a general hospital	1.097

Appendix C

Table C1 Comparison of study patients and patients admitted to all Dutch acute care hospitals in 2004

Patient data	Dutch population*	Total sample (weighted)†	Dutch population deceased patients‡	Sample deceased patients (weighted)¶
Number of inpatient admissions (% of all patients/of all deceased patients in Dutch hospitals in 2004)	1 343 234	7926 (0.6%)	42 329 (3.2%)	3983 (9.4%)
Number of admissions in university hospitals (% of total population/sample)	179 998 (13.4%)	1378 (17.4%)	4972 (11.7%)	780 (19.6%)
Age in years (mean (SD))	55.9 (21.7)	57.5 (21.5)	73.4 (13.9)	73.9 (13.4)
Men (%)	49.7%	49.1%	53.4%	53.8%
Admission duration in days (mean (SD/median))	7.3 (10.4/4.0)	8.5 (10.5/5.0)	12.1 (15.8/7)	12.3 (15.6/7)
Urgent admissions (%)	46.6	53.7	81.0	87.9
Hospital admission department (%)				
Surgery	24.4	24.0	13.5	11.7
Cardiology	16.1	12.9	16.9	13.3
Internal medicine	16.1	15.8	33.4	31.1
Orthopaedics	8.7	10.4	1.6	1.8
Neurology	6.3	7.4	13.0	12.3
Lung diseases	6.5	7.2	13.6	13.5
Ear, nose and throat	4.5	4.3	0.3	0.3
Urology	5.0	4.2	1.4	1.3
Other	18.8	14.5	11.1	14.7

*All admissions in non-specialty and non-psychiatric acute care hospitals in the Netherlands in 2004 (Source: Prismant); hospitals with fewer than 200 beds and psychiatric and obstetric patients and patients <1 year were excluded. Admissions less than 1 day were excluded in the discharged patient group.
†Psychiatric and obstetric patients and patients <1 year were excluded. Day admissions were only excluded in the discharged patients. Figures were weighted for oversampling of deceased patients and of patients admitted to a university hospital.
‡All deceased patients in non-specialty and non-psychiatric acute care hospitals in the Netherlands in 2004 (Source: Prismant); hospitals with fewer than 200 beds and psychiatric and obstetric patients, patients <1 year and day admissions were excluded.
¶Psychiatric and obstetric patients and patients <1 year were excluded. Figures were weighted for oversampling of deceased patients admitted to a university hospital.